



Getting quality testing closer to patients

ANNUAL REPORT 2019



Because diagnosis matters

OUR VISION

A world where diagnosis guides the way to health for all people

OUR MISSION

Turning complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives

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LEADERSHIP MESSAGE



Mark Kessel
Chairman of the Board
of Directors



Dr Catharina Boehme
Chief Executive Officer

As the end of our current strategy period approaches, we are happy to report that progress in 2019 ensures we are well placed to achieve the ambitious targets we set ourselves back in 2015. In July this year we gained ISO certification for our quality management system, related to clinical trials evaluating the performance of *in vitro* diagnostics for infectious diseases. This is an important step for our organization, assuring manufacturers and policy makers of the quality of the evidence we generate. We were also pleased to see FIND recognized as a high performer (one of 17 out of 198 organizations) in the 2019 Global Health 50/50 report on gender equality policies and practices.

Programmatically, our greatest achievements this year were in laboratory strengthening and evidence generation, with diagnostic capacity strengthened in nearly 650 laboratories or sites, and over 2,200 health workers trained. FIND Geneva has now become a preferred supplier to the Global Fund to Fight AIDS, Tuberculosis and Malaria for laboratory strengthening.

Since 2013, FIND has supported Indian company Molbio Diagnostics with the development of their point-of-care molecular platform Truenat™. Work in 2019 culminated in the Truenat tuberculosis (TB) test being endorsed by the World Health Organization (WHO) in January 2020. The India national TB control programme placed a tender for over 1,500 devices, setting a target of 5.9 million tests in 2020. Our TB diagnostic network optimization activities continue to influence national decisions, and this year we ascertained that the recommended network design for the Philippines allowed the national programme to make a US\$21 million saving, which can be redirected to other case finding and management activities.

Improving malaria diagnosis and differentiating that disease from other causes of fever remains a key area of focus. This year we supported local registration of a new rapid test that uses a finger-prick blood sample to simultaneously detect malaria infection and presence of C-reactive protein (an indicator for possible bacterial infection). By combining these two tests, healthcare workers will not only be able to diagnose malaria but will also have data for action if the malaria test is negative. Another diagnostic tool for malaria launched this year was the first commercially available molecular diagnostic test to detect malaria caused by *Plasmodium vivax* parasites even in low-transmission settings, making an important contribution to global elimination efforts as *P. vivax* is the next most important malaria target after *P. falciparum*.

Our work in Nigeria to support the national reference laboratory to build capacity for response to seasonal Lassa fever outbreaks reduced time to test results from days to hours. We also entered into a partnership with CEPI to expand our Lassa fever response programme in the country to enhance the development and deployment of vaccines and medicines.

An important milestone was reached this year by Uganda: with FIND support, the country was the first to submit a dossier to WHO evidencing the elimination of sleeping sickness (per WHO criteria). Schistosomiasis became the latest addition to our portfolio of neglected tropical diseases – a parasitic infection that can be picked up just from coming into contact with contaminated water. Identification of communities requiring mass drug administration depends on accurate diagnosis, which requires multiple samples collected over several days to be analysed by highly trained microscopists. Tests are also critical to determine treatment success, as inaccurate results can lead to the drug administration programmes being stopped too soon, and infections quickly returning to initial levels.

Exploratory work also began on non-communicable diseases (NCDs) in 2019. NCDs are increasingly associated with development and severity of infectious diseases in LMICs: around 20% of patients with multi-morbidities have been found to have both an infectious disease and an NCD, and we see potential opportunities to help fill significant diagnostic gaps.

Finally, this year we seized important opportunities to raise the visibility of the role of diagnostics, and to support those who are making a difference in improving access to testing in low- and middle-income countries (LMICs). We contributed to The Lancet Commission for TB (a roadmap for countries to achieve global commitments towards ending the TB epidemic), and we took part in the G20 Health & Development Partnership Summit, which culminated in a call to action with recommendations for ensuring progress towards SDG3 and universal health coverage. On World Hepatitis Day, we launched successful campaigns in partnership with both the Malaysian and Indian governments to improve screening for hepatitis C. At an event held during the World Health Assembly in May, we awarded the Voices for Diagnosis prize to community initiatives in South Africa, Uganda and India that are taking innovative approaches to decrease inappropriate prescription of antibiotics through better use of diagnostics.

FIND continued to grow in 2019, and we welcomed two new senior members to our team: Morten Ruhwald joined as Head of our TB programme in April, and Sergio Carmona as Director of TB, HIV and HCV in September.

At the very end of the year, reports of the novel respiratory pathogen SARS-CoV-2 began to emerge, and our pandemic preparedness team as well as FIND leadership immediately started working with WHO, Africa CDC and other partners to help boost diagnostic capacity in order to understand what was happening. COVID-19 has since then affected our lives and our work in an unprecedented way that is of course having a major bearing on our organization in 2020.

On behalf of FIND, we would like to thank you all: the FIND team, our partners, our funders, the patients who participated in clinical trials, and all those who have been instrumental in the 2019 achievements. Together we can continue to innovate and deliver game-changing tests that put patients on the road to health.

Mark Kessel, Chairman of the Board of Directors
Catharina Boehme, Chief Executive Officer

2019 IN NUMBERS



17 million

FIND-supported products estimated to have been provided to low- and middle-income countries (LMICs) (13% increase from 2017)



4

FIND-supported products achieved WHO recommendation



44

clinical studies/trials active in 30 LMICs, with 29,759 participants enrolled



52,738

patient samples collected for the FIND specimen bank



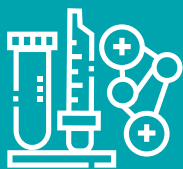
6,663

patient samples collected and used in FIND-sponsored clinical studies



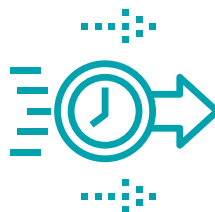
2,245

health workers trained across 40 LMICs



646

laboratories and testing sites strengthened in 18 countries in Africa, Asia, and Eastern Europe



14

projects progressed to next phase in development, with a total of 47 products in our pipeline



67

peer-reviewed manuscripts published by FIND authors – over 486 citations

COUNTRY OFFICE KEY ACHIEVEMENTS

Cape Town, South Africa

- Joined the TB Think Tank, which brings together experts from the government, academia and civil society to assist in guiding South Africa's TB response

- Established strategic partnerships and initiated the development of an openly available diagnostic network optimization tool

- Supported the design and planning of integrated sample referral systems (SRS) in 15 counties in Kenya, developed an operational guide to enable scale up to other counties, and facilitated revision of Kenya's national integrated SRS guidelines together with local partners and Ministry of Health

- Together with FIND India, initiated a TB diagnostic network optimization project aimed at optimizing access to TB molecular diagnosis and drug susceptibility testing towards reaching India's national strategic plan goals

- Raised awareness of the value of diagnostic network optimization through presentations at national and international fora

- Conducted usability and implementation studies of a TB point of care diagnostic, together with local partners in South Africa

- Contributed to evaluations of various diagnostic technologies in the Southern African region, including a TB LAM urine test and a stool processing method for TB diagnosis in children

- Continued work to support quality-assured antimicrobial resistance testing to improve appropriate antimicrobial use and strengthen surveillance efforts through development and piloting of laboratory and clinical assessment tools

- Continued contribution to policy, guidelines and tool development in collaboration with regional and global partners

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When most people think about where to establish research connections and partnerships in South Africa, they always think Durban, Johannesburg and Cape Town. As a newly established research unit in Eastern Cape province, we have not always found it easy to “break into” the existing networks and find international partners ready and willing to collaborate with us. FIND believed in us and our ideas from the very beginning and partnered with us to evaluate TB point-of-care diagnostic devices, and adapt available devices to allow for a home-based TB testing approach. True home-based TB testing may allow for improved case finding, early case detection and more rapid treatment initiation. We are hoping that what we are doing in Eastern Cape with FIND will inform national and global approaches to active TB case finding. We couldn't imagine a better relationship with a better partner.

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Andrew Medina-Marino, Head of Research, Foundation for Professional Development



New Delhi, India

- Tested over 740,000 patients for TB and drug-resistant (DR)-TB in FIND-supported laboratories, resulting in detection of nearly 14,000 cases of multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB, which were linked to treatment
- Upgraded and validated 3 TB liquid culture and drug susceptibility testing (C&DST) laboratories as part of a Global Fund-supported project in partnership with the National TB Elimination Program (NTEP). Another 7 laboratories are in the process of being upgraded and will be ready by the end of 2020
- Notified over 105,000 patients with TB seeking care in India's private health sector to the NTEP as part of the Global Fund supported project "Joint Effort towards Elimination of TB" (JEET), and ensured that at least 80% adhered to treatment; nearly 18,000 private sector providers have been sensitized on TB guidelines in 2019
- Supported the development of a "laboratory information management system" connecting the NTEP's TB C&DST laboratory network in India; 55 laboratories underwent training and were linked to NTEP's "Nikshay" web portal. Completed the development of a logistics module to support inventory management across the laboratories
- Screened 76,000 people for hepatitis C virus (HCV) as part of the Unitaid-funded HEAD-Start project, with over 9,000 cases of HCV detected and more than 5,000 patients linked to treatment

- Screened 2,300 prison inmates in the State of Punjab for HCV under the Gilead-funded project "Supporting hepatitis C micro-elimination among prison inmates in Punjab, India". Of those screened, 400 individuals were found to be HCV RNA positive, and around 70% of those were initiated on HCV treatment

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Private sector engagement is one of the key priorities of the National TB Elimination Programme (NTEP). The efforts of FIND and other partners of the Joint Effort for Elimination of TB (JEET) consortium have been critical in mounting an effective intervention to engage the private sector efficiently and provide diagnostic and treatment adherence support to patients treated in the private sector. The NTEP has achieved a record number of private sector notifications in 2019 and I would like to acknowledge the contribution of FIND and partners in this achievement.

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Dr K.S. Sachdeva, Deputy Director General, Central TB Division, National TB Elimination Program, Ministry of Health and Family Welfare, Government of India



Hanoi, Viet Nam

- Collaborated with the Viet Nam National Tuberculosis Control Program (NTP) on the evaluation of computer-aided detection solutions for pulmonary TB. Our work together also led to the collection of well-characterized specimens from Vietnamese patients with TB, which will allow us to diversify the FIND specimen bank geographically and support the development of new TB diagnostics

- Undertook an assessment with the National Institute of Malariology and Parasitology and Epidemiology to determine the prevalence of less common *Plasmodium* (malaria) species in Viet Nam using molecular diagnostic techniques. The study has contributed to establishing a specimen bank to support the development of high-performance, non-invasive malaria diagnostic tests for all types of *Plasmodium* species

- Together with USA CDC, supported the Viet Nam National TB Reference Laboratory in achieving proficiency testing for the Xpert MTB/RIF assay – a test that can diagnose TB and drug resistance in less than 2 hours. In demonstrating its performance to undertake this test to a high standard, the laboratory achieved ISO/IEC 17043:2010 in 2019 and is now preparing to become a regional External Quality Assurance (EQA) provider in 2020

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FIND has provided NTP with extensive support which has allowed us to achieve proficiency testing for the Xpert MTB/RIF assay. This milestone is critical in improving the quality of Xpert testing for TB nationally, and it will further benefit the region when NRL becomes a regional EQA provider.

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**Assistant Professor Viet Nhung Nguyen,
Chairman, National Tuberculosis Control Program.**



SPOTLIGHT

DR SERGIO CARMONA

Director of the HIV, TB and HCV programmes, FIND



I trained as a pathologist in South Africa in the field of haematology-oncology, specializing in haemato-pathology, which led me to the molecular testing laboratory for HIV, TB and haematology at the Charlotte Maxeke Hospital in South Africa, followed by the National Health Laboratory Services (NHLS). At the NHLS I was able to focus my efforts on the serious HIV epidemic that faces South Africa and the continent, through collaborative projects with national, regional and international organizations. This included supporting WHO with the development of clinical governance for testing and treating people with HIV and undertaking the role of principal investigator for Africa Centres for Disease Control and Prevention (Africa CDC)'s collaborative agreement for laboratory strengthening.

Joining FIND was a natural next step, allowing me to bring my skills, experience and network to the role of Director of TB, HIV and HCV programmes to have a global impact. I was particularly attracted by FIND's global health footprint – its work spans the development of early diagnostic tools to collaborating with industry and policymakers on evidence generation and testing, through to approvals, manufacturing and access.

In my new role, I strategically oversee the TB, HIV and HCV programmes. This means that I am constantly looking for innovative ways to engage industry with local manufacturing, ensure country engagements take place to assist with the development of diagnostic tools, help advance new service delivery models for testing, and ensure that emphasis is placed on strengthening the relationships between countries.

FIND is a unique organization with a clear role to play in diagnostics. As an established WHO Collaborating Centre, it is a hub of knowledge, technological expertise and access in an intricate field – and I am glad to be part of it.

STRATEGY & PROGRESS

Our work is guided by our 2015–2020 strategy, which focuses on our role as bridge builder and mobilizer, translating the technical world of product development into access to diagnostic solutions that meet patient needs in low-resource settings.

The strategy comprises four pillars, shown in Figure 1, together with key indicators of our achievements so far during this strategic period.



Figure 1: Bridging science and patients progress through our 2015-2020 strategic targets

HIGHLIGHTS

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) is a global health emergency: decades of medical progress are under threat as our ability to treat infectious diseases reliably with antibiotics is compromised. Bacteria will eventually develop resistance to all antibiotics. Some infections are already showing high levels of resistance, such as super-gonorrhoea, and are particularly dangerous because they are easily transmitted and difficult to accurately diagnose. Resistance to antibiotics can develop rapidly when antibiotics are used to treat the wrong infection or non-bacterial infections, which makes diagnosing the specific cause of the infection so critical. Diagnostics enable the optimal use of existing drugs and the protection of new treatments. A simple diagnostic test flagging the presence or absence of a bacterial infection can dramatically cut antibiotic overuse. Rapid tests can reduce the time to pathogen identification and facilitate faster, optimized antimicrobial treatment. Diagnostics also allow for active surveillance of drug resistance, data that can be used to effectively target health interventions and ultimately save costs.

We are working with our partners and donors to tackle AMR holistically by focusing on urgent unmet needs across the spectrum of R&D and access by:

- *Developing new tests specifically designed to address AMR, such as stewardship diagnostics that will help to safeguard new medicines*
- *Addressing barriers to diagnostic access that must be overcome to enable the use and impact of both existing and new tests*
- *Building diagnostic connectivity solutions that can facilitate and strengthen AMR surveillance*



FIND joins the CARB-X Global Accelerator Network

This year FIND joined the CARB-X Global Accelerator Network (CARB-X), a global partnership created to help address the threat of antibiotic resistance. We offer our expertise to CARB-X's diagnostic investments to ensure they have maximum impact against AMR, and we support new applicants for CARB-X funding in the development of new diagnostics – including assessment for use in resource-poor settings.

CARB-X's portfolio is evolving rapidly to bring new antibiotics, rapid diagnostics and other life-saving products to the fight against drug-resistant bacteria. The organization's global network of accelerators, including FIND, will bring the necessary scientific, technical, and business expertise to support its growing pipeline.

Development of new diagnostic tests for gonorrhoea

After chlamydia, gonorrhoea is the most common sexually transmitted infection (STI), with an estimated burden of 87 million cases worldwide. One of the major challenges in low-resource settings is the lack of affordable, fast tests to identify gonorrhoea from other causes of STI, which means that the wrong antibiotic treatment is easily prescribed. This contributes to the growing problem of drug-resistant infections.

Tests are urgently needed to allow rapid and accurate diagnosis in primary care settings, and to guide the appropriate use of existing and potential new treatments. Following a competitive request for proposal process, three tests were selected based on their ability to meet the target product

ANTIMICROBIAL RESISTANCE

profile (TPP) developed by FIND and WHO. Awards were made to Axxin and a consortium comprising QuantuMDx and Speedx for the development of molecular point-of-care gonorrhoea tests, and to DCN Diagnostics for the development of a rapid lateral flow assay for gonorrhoea. A design-locked test is expected to be ready in mid-2021.

AMR laboratory scorecard training in Viet Nam

In April we joined Bach Mai Hospital and BD (Becton, Dickinson and Company) in organizing a 2-day AMR laboratory quality scorecard assessors training at Bach Mai Hospital. The scorecard aims to positively impact AMR through several approaches, including the use of diagnostics to reduce unnecessary antibiotic prescribing, and improving surveillance for the early detection of drug resistance in hospitals and laboratories. Twenty-seven participants attended from seven hospitals in the north, central and south of Viet Nam, and the Government Medical College in Aurangabad, India.

Neonatal sepsis study begins

FIND signed an agreement with Tygerberg Hospital in South Africa to begin a neonatal sepsis study that will evaluate a new clinical score for the diagnosis of neonatal sepsis and the use of existing point-of-care-testing to improve antibiotic stewardship. Neonatal sepsis remains a major factor contributing to mortality and morbidity in newborns in LMICs; the identification of tools that can aid in timely and accurate diagnosis and management is critical.



One Health connectivity solutions

Under the guidance of Zambia's AMR Coordinating Committee (AMRCC) and the Zambia National Public Health Institute (ZNPHI; a technical arm of the Ministry of Health), FIND has been working to develop digital tools that can automatically extract One Health data from the health system for national and global reporting. These tools will retrieve data from existing systems in reference laboratories, such as the University Teaching Hospital, as well as data systems used by the Ministry of Fisheries and Livestock, and the Zambia Medical Regulatory Authority (ZAMRA). FIND has also helped create dashboards for easy visualization and analysis of the One Health surveillance data collected.

AMR Dx Use Accelerator prepares for global multi-site study

The AMR Diagnostic (Dx) Use Accelerator is a platform to evaluate a package of interventions and provide evidence to inform policy change that can positively impact AMR and contribute to universal health coverage. This year we began to prepare for a multi-site, randomized controlled trial of nine sites in six LMICs, focused on interventions to improve management of patients presenting with fever. The study will evaluate a "toolbox" that includes diagnostic tests, diagnostic aids and information to support healthcare professionals to identify the underlying cause of fever and rationalize the use of antibiotics.



HIGHLIGHTS

HEPATITIS C & HIV

With over 70 million people infected, hepatitis C is one of the world's most common infectious diseases, but 4 out of 5 people infected don't know it and only 15% receive treatment in the same year they are diagnosed. Hundreds of thousands of people die from the disease every year, and numbers are on the rise. It is usually contracted through unsafe healthcare practices or injection drug use, and the vast majority of people with hepatitis C virus (HCV) live in LMICs.

We are working with our partners and donors on simple diagnostic solutions that can be integrated into existing care pathways to slow disease transmission, and reduce the morbidity, mortality and socio-economic impact of viral hepatitis. Our activities are focused on three key areas, under the umbrella of the Unitaid-funded HEAD-Start (Hepatitis C Elimination through Access to Diagnostics) programme:

- *Supporting the development of affordable, fit-for-purpose diagnostics that can be used at the point of care and the community level*
- *Facilitating access to diagnosis and enabling the prevention of infection by interventions including cost-saving, effective integration of HCV care into HIV public health programmes*
- *Demonstrating the need and benefit of interventions for HCV by championing HCV prioritization in national agendas, and driving policy change and simplification of the HCV testing algorithm.*



Advancing the HCV diagnostics pipeline

In 2019 we made good progress advancing the HCV diagnostics pipeline, completing feasibility studies on a core antigen rapid diagnostic test (cAg RDT), which led to the launch of an expression of interest for prototype development. The cAg RDT could be a game changer for HCV point-of-care confirmation, allowing same-day test-and-treat without the need for complex infrastructure. We also began studies on several manufacturer protocols for dried blood spot (DBS) sampling. DBS is a convenient tool for diagnostic testing for viral diseases that has several advantages over blood samples, including ease of transport and handling, and could allow for HCV testing to be integrated into existing sample transport networks. We completed the first of many studies on the feasibility and acceptability of HCV self-testing in Egypt, China, and Viet Nam.

Harm-reduction site testing in Georgia

Georgia has a high prevalence of HCV, with 40% of the infections being contracted through injection drug abuse. Through HEAD-Start, we are bringing HCV testing to harm-reduction sites across the country, where we have been able to reduce loss to follow up between a first HCV test and the second confirmatory test, from over 50% to 0% loss during the course of our study. As people who inject drugs can find it challenging to access medical care, we are also ensuring that those testing positive have access to treatment, and continuing research to better understand the risk of reinfection within this population.

HEPATITIS C & HIV



Community-based testing and treatment in Myanmar

In Myanmar, we are working with the Burnet Institute in partnership with Myanmar Liver Foundation (MLF) to implement a community-based 'one stop shop' testing and treatment study that will support national strategic planning for decentralization of HCV diagnosis and care. Eight technicians were trained at two study sites on the HCV rapid diagnostic tests and point-of-care HCV RNA testing. Patients are enrolled and treated for HCV either at a neighbourhood charity clinic or a neighbourhood drop-in centre for people who inject drugs.

Malaysia: #MYmissingmillions

Building on the success of the HEAD-Start Malaysia study, which introduced HCV rapid diagnostic tests to the primary healthcare system, we partnered with the Drugs for Neglected Diseases *initiative* (DNDi) and the Ministry of Health in Malaysia to launch the country's biggest-ever screening initiative for HCV. The #MYmissingmillions campaign was announced ahead of World Hepatitis Day 2019, to raise awareness of the importance of early HCV diagnosis and to ensure that all Malaysians have the opportunity to be tested and receive treatment for free.

The partnership offered Malaysians free screening in July using a simple rapid diagnostic test at primary healthcare sites – the first time that rapid tests have been used for HCV nationally. The model developed by the HEAD-Start study will now be scaled up through a change in national policy, enabling screening and treatment to be decentralized for the first time and delivered through primary care.

HEAD-Start making an impact across India

In India it is believed that anywhere between 6 and 12 million people are infected with HCV – so tackling the issue has become a national priority. The HEAD-Start initiative brought together the National Viral Hepatitis Control Program (NVHCP) and the National Aids Control Organization programmes (NACO) for the first time as a foundation for integration to discuss HCV service delivery for co-infected populations, better understand the uptake of HCV services across states and integrate NVHCP activities into other health delivery services.

Progress has been made in three key areas of the country. In Manipur, a memorandum of understanding with the local government, Manipur State Aids Control Society, and YR Gaitonde Centre for AIDS Research and Education has allowed more than 3,000 people to be screened for HCV, and those testing positive (over 700 people) to be treated. In Delhi, the Ministry of Health endorsed HEAD-Start as a well-functioning 'Delhi Model', with five hospitals and 15 polyclinics now offering HCV testing and treatment services, enabling 30,000 people to be screened. In Punjab, 26,000 people have been screened for HCV, and the focus is now on ensuring those testing positive receive treatment. Separately, in Punjab we rolled out a unique initiative supported by Gilead to screen and treat prison inmates – another population classified as being at high risk for HCV infection.



HIGHLIGHTS

MALARIA & FEVER

Management of fever (febrile illness) is a huge medical challenge. In Africa alone, over 600 million childhood fevers occur every year. Many febrile illnesses, especially in children, present with highly non-specific and overlapping signs and symptoms that are difficult to distinguish clinically. This is largely because the tools available to health professionals for diagnosing and managing childhood illnesses are limited in resource-poor settings.

In some countries – particularly in Africa – the cause of the fever is very often malaria. Malaria is ambitiously targeted for global elimination by 2030, but in recent years progress in reducing new malaria cases has levelled off. The latest World Malaria Report estimated that there were 228 million cases of malaria in 2018, compared with 251 million cases in 2010, while the number of deaths from malaria had remained stable since 2017.

As well as supporting malaria elimination efforts, we are working with our partners and donors on diagnostic solutions that can inform optimal treatment solutions for all patients presenting with fever. Our work is therefore focused in three areas:

- R&D for improved malaria diagnostics that can detect the disease in hard-to-diagnose populations, differentiate between parasite strains to inform treatment decisions and facilitate the introduction of targeted treatments, and support elimination strategies
- R&D for fever diagnostics that can identify the cause of fever when it is not malaria, based on likely pathogens in specific geographic areas, and help to guide appropriate treatment, promoting patient care and antimicrobial stewardship

- Addressing barriers to access and appropriate use of quality diagnostics that must be overcome to enable the use and impact of both existing and new tests, including the deployment of technological solutions to support implementation.



Commercial launch of first molecular test for *P. vivax*

With partners HUMAN and EIKEN, we launched the first commercially available molecular diagnostic test for the detection of malaria caused by *Plasmodium vivax* parasites. *P. vivax* accounts for more than half of all malaria cases outside sub-Saharan Africa, but its clinical characteristics make it particularly difficult to detect.

Malaria-LAMP is the first molecular test that can identify *P. vivax* infections even in low-transmission settings, making a significant contribution to global elimination efforts. The test can differentiate between *Plasmodium pan*, *P. falciparum* and *P. vivax* species, and has a sensitivity of 84–94%, a specificity of >92% and a limit of detection of 1–2 parasites/μL. FIND evaluated the prototype test in collaboration with the Hospital for Tropical Diseases in London, UK, and coordinated in-country clinical performance studies in Colombia and Peru.

A country-led approach for lasting impact

This year we established formal collaborations with government partners in several countries across Africa and Asia: Burkina Faso, Senegal, Cambodia, Bangladesh, Myanmar and Viet Nam. These new partnerships have already spurred projects and studies in which the country partners (i.e. the Ministries of Health or the National Malaria Control Programmes) are taking a leading role. This country-led, impact-driven approach will

MALARIA & FEVER

play a vital role in ensuring the sustainability of malaria control and improved fever management and surveillance on the ground.

Completed patient enrolment of the largest-ever study to evaluate fever biomarkers

Treating patients with fever in malaria endemic settings remains a clinical challenge primarily due to the lack of tools to identify the cause of fever. To address this gap, we completed patient enrolment for the largest-ever study evaluating fever host-biomarkers, which are indicators that can help guide care decisions and particularly indicate if a patient needs antibiotic or not. With partners including the Malawi Epidemiology and Intervention Research Unit (MEIRU) in Malawi, FIOCRUZ in Brazil, and the Center of Medical Research Lambaréné (CERMEL) in Gabon, we collected samples of disease in more than 1900 individuals in those countries. The analysis of the sample collection is ongoing; the collection is now accessible to researchers and companies and will facilitate the development of future fever-related diagnostic tests.

Evaluation of STANDARD™ Q Malaria/CRP Duo Test in India and Gabon

As part of our work on fever biomarkers we have also undertaken studies to evaluate the performance of commercial tests that can identify both malaria and possible bacterial infections (via a host-biomarker), helping care providers to prescribe the right treatment. We evaluated the STANDARD™ Q Malaria/CRP Duo Test, which received CE marking in 2018, to support local registration in India. The first results for India and Gabon were presented at the 68th Annual Meeting of the American Society of Tropical Medicine and Hygiene in November 2019.



HIGHLIGHTS

NEGLECTED TROPICAL DISEASES

As a group, neglected tropical diseases (NTDs) affect more than 1 billion people – and cost economies billions of dollars – every year. These diseases have suffered a historical lack of attention, largely because they thrive in conditions of poverty. Beyond their neglect, NTDs have little in common, being caused by a variety of pathogens, ranging from viruses to bacteria, fungi, protozoa, and helminths.

Diagnostics are critical for control and elimination of NTDs. They are also important for surveillance, with large-scale screening initiatives needed to track down the last cases so that they can be treated and do not become a source of infection for others. Diagnostics can be used to confirm or rule out disease following a positive screening test. They are also a crucial complement to treatment strategies, monitoring treatment response in individuals as well as the success of public health initiatives such as mass drug administration.

The FIND NTD portfolio focuses on those with significant unmet diagnostic needs, particularly human African trypanosomiasis (HAT; also known as sleeping sickness), leishmaniasis, Buruli ulcer and schistosomiasis.

Together with our partners and donors, we are working on diagnostic solutions that can address the lack of readily available, easy-to-use, reliable and low-cost diagnostic tools to identify infections, detect disease re-emergence, monitor the impact of mass drug administration and guide delivery of appropriate control measures.



Our work supports the targets defined in the WHO Roadmap on NTDs and the London Declaration on NTDs – as well as SDG3 – in two specific areas:

- *Interrupting transmission of HAT, Buruli ulcer and visceral leishmaniasis (Indian subcontinent) through early diagnosis*
- *Driving elimination of schistosomiasis through improved diagnostics.*

New efforts to eliminate schistosomiasis

This year we launched a new programme that aims to support efforts to eliminate schistosomiasis, a disease caused by parasitic worms released from freshwater snails that affects 78 countries in subtropical and tropical regions.

We are leading a consortium of partners, including WHO, dedicated to developing an affordable rapid diagnostic test (RDT) to identify the disease. Existing diagnostic tools require a time-consuming process and are costly; an RDT would provide timely, valuable data on the prevalence and intensity of the infection, enabling targeted treatment to break the cycle of infection.

Since the launch of the partnership, we have made good progress, developing a promising prototype Gen 1 RDT that detects an antigen that is specific to all schistosomes of public health importance. The Gen 1 RDT moved from feasibility to development stage this year.

NEGLECTED TROPICAL DISEASES

A step closer to eliminating sleeping sickness

Sleeping sickness (*gambiense* human African trypanosomiasis, or gHAT), a disease that is usually fatal if not treated, is transmitted to humans through the bite of an infected tsetse fly. Following sustained control efforts, the number of reported cases has dropped to less than 1,000 in 2018.

This year saw a 3-year extension of the Trypa-NO! project, a partnership between FIND, the French National Research Institute for Sustainable Development and the Liverpool School of Tropical Medicine. The additional work aims to further support the validation of the elimination of the disease in Uganda and Ivory Coast, drive cases to zero in Chad and Republic of Guinea, and expand the programme into South Sudan, Central African Republic and Sierra Leone.

In 2019 we also continued surveillance-based sleeping sickness elimination activities in Angola, Republic of Congo and South Sudan, thanks to additional funding from the Republic and State of Geneva, Switzerland.

Diagnostics innovations for Buruli ulcer

Buruli ulcer is a necrotizing disease of the skin that can lead to permanent disfigurement and disability, and that affects primarily children under the age of fifteen. Early diagnosis is key to reducing the burden of the disease and preventing long-term disability, but the current standard diagnostic method is complex and can take a month or more to obtain test results.

We worked with the Swiss Tropical & Public Health Institute on a rapid diagnostic test for Buruli ulcer which in 2019 moved from feasibility to development stage. This test can be used at the point-of-care so that providers can prescribe treatment immediately.

In December, we also started a partnership with the Noguchi Memorial Institute for Medical Research (Legon, Ghana) to assess the performance of a new prototype based on DRB-LAMP technology. This new test could also detect infection in a timely manner, and could be used at the point-of-care in resource limited settings.



HIGHLIGHTS

PANDEMIC PREPAREDNESS

Global health security is an ever-present concern. Pandemics caused by emerging and re-emerging infectious diseases put lives, health and prosperity at risk. While outbreaks are often unpredictable, this is not always the case; Lassa fever, for example, appears every year in Nigeria, but few regulatory-approved diagnostics – and no vaccines or medicines – are available.

Diagnostics are fundamental to the identification, containment and eventual resolution of disease outbreaks. Poor diagnostic capacity compromises surveillance activities, outbreak detection and response, both at a national level and in community healthcare settings. In the case of the 2013–16 Ebola epidemic in West Africa, it took 3 months to figure out that the infection was indeed Ebola. That delay resulted in the loss of thousands of lives and billions of dollars in the cost of response.

Together with our partners and donors, we are working to strengthen diagnostic preparedness for the WHO R&D Blueprint pathogens, as well as yellow fever, dengue and bacterial meningitis. Activities are organized across three areas:

- *Identifying technical solutions that will close R&D gaps, including diagnostic platforms that can support tests for multiple pathogens, with enhanced connectivity to enable swift identification of an outbreak*
- *Improving outbreak response speed by ensuring readiness to conduct robust clinical trials at short notice, supported by regulatory pathways that can expedite approval of successful diagnostic candidates*

- *Supporting market sustainability by exploring innovative new financing solutions, procurement and supply mechanisms, for ongoing affordability and availability of critical diagnostics.*



Advancing Zika diagnostics

Zika cases have decreased significantly since 2016, but the disease is still present in over 84 countries. Zika is primarily transmitted through the bite of an infected mosquito and can cause severe developmental defects in an unborn child. Surveillance and monitoring are key to ensuring that outbreaks are contained and transmission is minimized.

Several diagnostic tools for the Zika virus are currently available, however their performance has not been assessed in a standardized way. This year we began working with the WHO Zika Task Force to address this gap, by evaluating molecular and serological assays using reference panels developed by the Vitalant Research Institute (VRI). Six molecular and 14 serological assays were selected for the first round of the evaluation, which will start in 2020.

We also began assessing the feasibility of a virtual biobank network to facilitate access to well-characterized samples from individuals infected with Zika and other arboviruses for the development and validation of diagnostics. Through interviews with experts and key opinion leaders we have been able to finalize a strategy for a Zika virtual biobank that may also be helpful for other outbreak-prone pathogens.

PANDEMIC PREPAREDNESS



Enhancing the response to Lassa fever

Lassa fever is an acute viral haemorrhagic illness caused by a virus carried by rodents and is endemic in several West African countries, including Nigeria. An estimated 100,000 to 300,000 people are infected annually, with approximately 5,000 deaths, but the lack of standardized surveillance and diagnostics poses a challenge for detection and response to outbreaks.

To support research and development to increase access to Lassa virus diagnostics, we have been working to make the laboratory-based molecular (manual PCR) tests more widely available, as well as exploring novel partnerships to develop simpler, automated PCR tests. To this end, we evaluated a prototype Lassa Fever Flex Cartridge in Nigeria, co-developed by Altona Diagnostics and Cepheid, and we finalized discussions to include the Altona Lassa Fever RT-PCR 2.0 molecular assay on the BLINK One platform, a novel automated point-of-care system. Antibody (serological) tests for Lassa fever are important for surveillance and can also be considered to support clinical management.

To strengthen capacity to better respond to seasonal outbreaks, in collaboration with Nigeria's National Centre for Disease Control (NCDC), we conducted a series of trainings for five laboratories throughout the region to support the

expansion of the Nigeria Lassa Fever Testing Network. By appropriately adding more well-trained laboratories capable of Lassa fever diagnosis, we can enable a reduction in the time for availability of test results from days to hours.

Innovation for yellow fever diagnostics

Despite the existence of an effective vaccine, the burden of yellow fever has been estimated at 51,000–380,000 severe cases and 19,000–180,000 deaths in Africa alone in 2013. From 2016 to 2018, the largest yellow fever outbreaks in decades were reported in Africa and South America. An outbreak can spread rapidly between the time a yellow fever case is suspected to receiving confirmation from laboratory results. Currently, it can take up to 1 month to confirm a suspected case in Africa. To address this gap, we have been working with Mologic to develop the NS1 rapid diagnostic test (NS1 RDT), one of the first rapid tests for yellow fever. The test moved from concept stage to feasibility stage this year.

As part of a project with Gavi, the Vaccine Alliance, and WHO to assess diagnostic needs impacting the availability and use of the yellow fever vaccine, we also developed a target product profile for yellow fever molecular assays, immunoassays and rapid diagnostic tests.

The Sydney Statement on Global Health Security

Contributing to the global discussion on the management and response to outbreaks, while raising awareness about the role of diagnostics, is one of the programme's priorities. At the 2019 Global Health Policy Forum (Geneva, Switzerland) we joined global leaders for discussion on innovation and systems thinking to meet global health challenges, including those posed by pandemics. The Global Health Security Summit (Sydney, Australia) focused on gaps and opportunities to enhance national, regional and global health security. Along with the other participating organizations, we helped to shape the "Sydney Statement on Global Health Security" and became a signatory to its principles for addressing global health threats with an inclusive and equitable approach.

HIGHLIGHTS

TUBERCULOSIS

Tuberculosis (TB) kills more people than any other single infectious disease, including HIV. Latest WHO data estimate that every year 10 million people develop the disease. LMICs overwhelmingly bear the highest burden, and the impact of the disease on individuals and communities is devastating. Every year, millions of TB infections go unidentified, preventing patients from accessing treatment, and allowing the disease to spread. Drug resistance is a growing threat.

Diagnostics are needed to detect exposure, diagnose disease and drug resistance, and monitor improvement under treatment in both primary healthcare and laboratory settings. Ensuring that the right tools are accessible where they are needed is not straightforward, and development of any new diagnostic test has to take into account the context in which it would be used.

We are working with our partners and donors to make easy-to-use, robust, reliable and highly accurate tests a reality in routine clinical settings, particularly at the lower levels of care.

Our R&D efforts are focused on areas of critical unmet need:

- *A user-friendly, low-cost, non-sputum-based rapid test for diagnosing active TB that can be used for active case-finding and in primary healthcare facilities*
- *Rapid drug-resistance tests that enable treatment regimens to be tailored to individuals and help to safeguard medicines against AMR.*



In parallel, we are developing strategies to increase and speed up access to both new and existing tools. We are also exploring digital technologies to enhance diagnostic connectivity and data utilization for optimal health impact.

Next-generation TB testing in HIV positive people

TB is the most common cause of death for people living with HIV in low-resource settings. Tests with high sensitivity are urgently needed to allow earlier diagnosis in this population. After a decade of research, the Fujifilm SILVAMP TB LAM test – a next-generation, urine-based, point-of-care test – has now completed development, with a sensitivity that is around 30% higher than the existing commercially available test. This test has the potential to transform TB testing in people living with HIV, and paves the way for non-sputum tests that can be used in other populations.

Collaboration with Unitaid on next-generation sequencing

This year we kicked off a new collaboration with Unitaid to evaluate the use of next-generation sequencing (NGS) for diagnosis of drug-resistant TB in low- and middle-income countries. The project, known as Seq&Treat, will be implemented across Brazil, China, Georgia, India and South Africa over 3 years, and will enable the global adoption of NGS solutions for affordable, scalable and rapid TB drug susceptibility testing.

TUBERCULOSIS

Boosting TB drug-resistance testing in India

A new initiative, supported by Johnson & Johnson and in collaboration with the country's Revised National Tuberculosis Control Programme (RNTCP), began to help build and strengthen the capacity of at least seven TB culture and drug-susceptibility testing (C&DST) facilities in India. We are working together to establish and enhance the capacity of TB C&DST laboratories in the high-burden TB states of Maharashtra, Himanchal Pradesh and Tamil Nadu.

Centralized assays for high-throughput testing

We conducted an external laboratory validation for four novel high-throughput TB assays (from Abbott, Roche, Hain and Becton Dickinson) that allow the detection of TB as well as resistance to isoniazid and rifampicin, antibiotics commonly used to treat TB. The aim of the assessment was to validate and expand upon the analytical data that the manufacturers have compiled. In addition, we performed a systematic review and meta-analysis of clinical performance data, including an assessment of operational characteristics, ease of use and cost. Experts convened by WHO agreed that the analytical performance of these novel assays is comparable with the performance of the Xpert MTB/RIF test.

New policy recommendation for Xpert and Truenat tests

Through systematic reviews and large clinical trials, FIND generated evidence that enabled WHO to provide a recommendation for the use of Xpert MTB/RIF and Xpert Ultra as initial diagnostic tests for pulmonary TB in patients of all ages. We also provided data to support the WHO recommendation for the use of Truenat MTB, MTB Plus and MTB-RIF Dx assays, from a large clinical trial showing comparable accuracy with Xpert for TB and sequential rifampicin resistance detection.

New guidance series for accuracy studies

Accuracy studies represent a fundamental step in the validation of diagnostic tests, but limitations in study design, execution and reporting can lead to uncertainty about the tests' real performance and delay policy and



scale-up decisions. To address this issue, we worked with WHO and 50 key opinion leaders to publish a guidance series for accuracy studies for novel TB diagnostic products. The series appeared in the *Journal of Infectious Diseases* and built on four WHO high-priority target product profiles (TPPs) which outline important needs for TB diagnostic development. By increasing clarity around those needs, the series aimed to support harmonized evidence generation to inform WHO's review process for novel TB tests that can advance progress towards meeting global TB targets.

Joint Effort for Elimination of TB (JEET)

Nearly half of all patients with TB in India first seek care in the private sector, where there are significant gaps across the patient-care cascade, diagnostic delays, irrational and non-standardized regimens, and under-reporting to authorities. As a result, more than a million cases of TB are estimated to be missed in India every year.

The Joint Effort for Elimination of TB (JEET) was set up by FIND and partners in collaboration with private sector physicians, laboratories and pharmacies in over 93 districts across various states of India, to increase identification and notification of TB, facilitate early treatment initiation and provide support for improved treatment completion rates. In 2019, the JEET project doubled patient notifications and significantly improved treatment outcomes for TB in the private sector. To date, over 105,000 cases of TB have been notified through the JEET project, with over 70% of patients having successful treatment outcomes.

FIND GOVERNANCE

Board of Directors

1. Mark Kessel (Chairman)
2. Daniel Camus
3. George F. Gao
4. David L. Heymann
5. Andrew Jack
6. Shobana Kamineni
7. Ilona Kickbusch
8. Carlos Morel
9. Marcel Tanner
10. Sheila D. Tlou
11. Michael Watson

SAC – Core members

1. Marcel Tanner (Chairman)
2. Manica Balasegaram
3. Madhukar Pai
4. Ana Rabello
5. Thomas White

Co-opted members are eligible for a 1-year membership and are invited to join the SAC based on their expertise across new technologies and disease areas.

FIND team – Senior Leadership

Chief Executive Officer: Catharina Boehme

Chief Access Officer: Zachary Katz

Chief Scientific Officer: Ranga Sampath

Director of TB, HIV & HCV: Sergio Carmona

Director of Finance: Louisa Chaubert

Director of Emerging Threats: Cassandra Kelly-Cirino

Director of Operations: Sharon Saacks

Director of Business Development & Resource Mobilization: Jon Bastow

Head of Human Resources: Béatrice Mouton

Head of Communications: Sarah-Jane Loveday

Head of Data Services & Biobanking: Stefano Ongarello

Head of Malaria & Fever: Sabine Dittrich

Head of Neglected Tropical Diseases: Joseph N'dung'u

Head of Tuberculosis: Morten Ruhwald

Head of FIND India: Sanjay Sarin

Regional Technical Director, FIND India: Sarabjit Chadha

Head of FIND South Africa: Heidi Albert

Head of FIND Vietnam: Van Anh Nguyen

THANK YOU TO OUR DONORS

Anesvad Foundation

Australian Government

Botnar Foundation

Bill & Melinda Gates Foundation

Centers for Disease Control and Prevention / African Society for Laboratory Medicine

Elma Foundation, South Africa

European Commission

European & Developing Countries Clinical Trials Partnership

The Global Fund to Fight AIDS, Tuberculosis and Malaria

Global Health Innovation Technology Fund

Government of Germany

Government of Netherlands

Government of Switzerland

KfW Development Bank

Probitas Foundation

Service de la solidarité internationale, République et Canton de Genève

TB Reach through Stop TB Partnership

UK aid from the British people

Unitaid

United States Agency for International Development / KNCV Tuberculosis Foundation

World Health Organization



FIND AUDIT REPORT 2019



Foundation for Innovative New Diagnostics (FIND), Geneva

Report of the Statutory Auditor
on the Consolidated Financial Statements
to the Board of the Foundation
Consolidated Financial Statements 2019



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Report of the Statutory Auditor to the Board of the Foundation of the
Foundation for Innovative New Diagnostics (FIND), Geneva

Report of the Statutory Auditor on the Consolidated Financial Statements

As statutory auditor, we have audited the accompanying consolidated financial statements of Foundation for Innovative New Diagnostics (FIND), which comprise the statement of revenue and expenditure, statement of changes in capital, balance sheet, cash flow statement, and notes for the year ended 31 December 2019.

Board of the Foundation's Responsibility

The Board of the Foundation is responsible for the preparation of the consolidated financial statements in accordance with Swiss GAAP RPC and the requirements of Swiss law. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error. The Board of the Foundation is further responsible for selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Those standards require that we plan and perform the audit to obtain reasonable assurance whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control system relevant to the entity's preparation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control system. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements for the year ended 31 December 2019 give a true and fair view of the financial position, the results of operations and the cash flows in accordance with Swiss GAAP RPC and comply with Swiss law.

Report on Other Legal Requirements

We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 728 CO and article 11 AOA) and that there are no circumstances incompatible with our independence.

In accordance with article 728a paragraph 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists, which has been designed for the preparation of consolidated financial statements according to the instructions of the Board of the Foundation.

We recommend that the consolidated financial statements submitted to you be approved.

KPMG SA



Pierre-Henri Pingeon
Licensed Audit Expert
Auditor in Charge



Cédric Rigoli
Licensed Audit Expert

Geneva, 26 May 2020

Enclosure:

- Statement of revenue and expenditure, statement of changes in capital, balance sheet, cash flow statement and notes

STATEMENT OF REVENUE AND EXPENDITURE FOR THE YEAR ENDED 31 DECEMBER 2019

(all amounts in US dollars)

	2019	2018
REVENUE		
Grant revenue	55,842,142	59,513,727
Other operating income	585,117	447,040
Total revenue	56,427,259	59,960,767
of which is restricted	54,682,828	58,321,515
EXPENDITURE		
Programme services		
Tuberculosis	10,181,810	9,276,383
AMR and Outbreaks	7,197,653	3,748,848
Fever and Malaria	4,938,400	5,506,213
Neglected tropical diseases	6,516,393	5,703,620
HCV and HIV	8,452,231	8,250,318
Access TB India	10,427,420	20,428,646
Access in other countries and cross cutting	3,352,827	2,345,430
Total programme services	51,066,734	55,259,458
Supporting Services		
Information & communication	185,802	186,535
Governing & advisory bodies	52,271	89,622
General administration	4,802,713	3,908,694
Depreciation & amortization	19,370	4,129
Total supporting services	5,060,156	4,188,980
Total operating expenditure	56,126,890	59,448,438
Operating result	300,369	512,329
Financial income	314,122	340,946
Financial expenses	139,592	116,039
Financial result	174,530	224,907
Result before changes in restricted funds	474,899	737,236
Change in restricted funds	1,843	(157,736)
Annual result before allocation to organization capital	476,742	579,500
Allocations/appropriation		
Free capital	(476,742)	(579,500)

The accompanying notes form an integral part of these financial statements.

STATEMENT OF CHANGES IN CAPITAL AS AT 31 DECEMBER 2019

(all amounts in US dollars)

	Balance 1.1.2019	Allocation	Use	Total change	Balance 31.12.2019
Restricted funds	467,099	(56,100,776)	56,102,619	1,843	465,256
Organization capital					
Foundation capital	40,430	-	-	-	40,430
Unrestricted surplus	4,916,046	476,742	-	476,742	5,392,788
Total organization capital	4,956,476	476,742	-	476,742	5,433,218

	Balance 1.1.2018	Allocation	Use	Total change	Balance 31.12.2018
Restricted funds	309,363	(58,321,515)	58,163,779	(157,736)	467,099
Organization capital					
Foundation capital	40,430				40,430
Unrestricted surplus	4,336,546	579,500	-	579,500	4,916,046
Total organization capital	4,376,976	579,500	-	579,500	4,956,476

BALANCE SHEET AS AT 31 DECEMBER 2019

(all amounts in US dollars)

	Note	2019	2018
ASSETS			
Current assets			
Cash and cash equivalents	8	40,871,808	37,815,208
Accounts receivable		2,226,115	300,560
Prepayments and accrued income		7,573,565	2,767,698
Total current assets		50,671,488	40,883,466
Non-current assets			
Fixed assets		46,645	5,317
Rental guarantee deposit		238,765	235,566
Total non-current assets		285,410	240,883
Total assets		50,956,898	41,124,349
LIABILITIES AND CAPITAL			
Current liabilities			
Accounts payable and accrued expenses		7,559,213	7,419,530
Deferred revenue	9	37,499,211	28,281,244
Total current liabilities		45,058,424	35,700,774
Restricted funds		465,256	467,099
Organization capital			
Initial foundation capital	13	40,430	40,430
Free capital		5,392,788	4,916,046
Total Capital		5,433,218	4,956,476
Total liabilities, capital and reserves		50,956,898	41,124,349

CASH FLOW STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2019

(all amounts in US dollars)

	2019	2018
Annual result before allocation to organization capital	476,742	579,500
Change in restricted funds	(1,843)	157,736
Add back non-cash charge - depreciation & amortization	19,368	4,129
Add back non-cash charge - net impact of foreign exchange rate differences on cash held	116,659	(1,222,919)
	610,926	(481,554)
Cash flows - operating activities		
Increase (decrease) in deferred revenue	9,217,967	(3,061,111)
Increase (decrease) in accounts payable and accruals	139,683	(2,571,762)
(Increase) decrease in accounts receivable	(1,925,555)	217,026
(Increase) decrease in prepayments	(4,805,867)	(299,982)
Net cash provided by operating activities	2,626,228	(5,715,829)
Cash flows - investing activities		
(Increase) decrease in rental guarantee deposit	(3,199)	(8,489)
Acquisition of computers & printers	(60,696)	-
Net cash used in investing activities	(63,895)	(8,489)
Net increase (decrease) in cash and cash equivalents for year	3,173,259	(6,205,872)
Cash and cash equivalents at start of year	37,815,208	42,798,161
Net impact of foreign exchange rate difference on cash held	(116,659)	1,222,919
Cash and cash equivalents at end of year	40,871,808	37,815,208
Net increase (decrease) in cash and cash equivalents for year	3,173,259	(6,205,872)

The accompanying notes form an integral part of these financial statements.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2019 (all amounts in US dollars)

1. General information

1.1 Legal aspects

The Foundation for Innovative New Diagnostics (FIND) is an independent Swiss Foundation established as a not-for-profit legal entity created under Article 80 of the Swiss Civil Code and registered in the Geneva Register of Commerce on 29 July 2003.

FIND's mission is to drive the development and early implementation of innovative diagnostic tests that have a high impact on patient care and disease control in low-resource settings.

FIND is monitored by the Swiss Federal Supervisory Board for Foundations.

1.2 Tax exemption

On 9 December 2010, FIND and the Swiss Federal Council signed an agreement granting FIND certain privileges and immunities under the revised Host State Act, which came into force on 1 January 2008. In accordance with this agreement, FIND has been granted exemption from all federal, cantonal and communal taxes, from Value-Added Tax, and from regulations governing the employment of foreign nationals in Switzerland. This agreement came into effect on 1 January 2011.

1.3 Regional offices

FIND is headquartered in Geneva, Switzerland and has regional offices in New Delhi, India; Cape Town, South Africa; Kampala, Uganda, Hanoi, Vietnam. Plans are currently underway to operationalise FIND DX Kenya.

Since 2007, FIND has played a key role in demonstrating the effectiveness of new diagnostics in country settings, and scaling up the delivery of strong programmatic management of drug-resistant Tuberculosis in India and South-East Asia. FIND India was established as a liaison office through a Collaborative Agreement with Ministry of Health & Family Welfare of the Indian Government. In addition, the Foundation for Innovative New Diagnostics India was incorporated under section 8 of the Companies Act as a non-profit company, limited by guarantee, in July 2015; this entity became operational in 2017.

FIND Uganda was established in 2008 and provides support for FIND's research and field activities for Tuberculosis, Malaria and Human African Trypanosomiasis in Uganda. It is established as a non-governmental organization on the basis of a Memorandum of Understanding with the republic of Uganda.

FIND Dx in South Africa was registered as a non-profit company in December 2014 and is FIND's principal representative office in Africa with a main focus on access-related work. This company has no share capital and is not limited by guarantee. FIND's operations as a non-governmental organization in Vietnam were registered with the People's Aid Coordinating Committee in August 2015. FIND's work in Vietnam aims to support research and treatment of infectious diseases, primarily tuberculosis, supporting the National TB Program, Pham Ngoc Thach Hospital and the National Institute of Malariology, Parasitology and Entomology.

FIND Dx Kenya was registered in May 2019. The office is to be operationalised in 2020. At the time of registration of FIND DX Kenya, FIND Geneva was already supporting a number of projects in the Ministry of Health and at KEMRI.

2. Significant accounting policies

2.1 Basis of presentation

These consolidated financial statements have been prepared in accordance with the Accounting and Reporting Recommendations Swiss GAAP RPC and more specifically with Swiss GAAP RPC 21 for charitable non-profit organisations. These consolidated financial statements gives a true and fair view which reflect the economic facts and are thus free of deception and manipulation.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2019 (all amounts in US dollars)

Consolidated financial statements are based on the individual financial statements established as at 31 December in accordance with single accounting principles for all entities within the group.

Significant items are accounted for as follows:

2.2 Cash and cash equivalents

Cash and cash equivalents comprise cash balances and short-term money market deposits with maturities of 3 months or less from the balance sheet date at the most.

2.3 Rental guarantee deposit

The deposits relate to the rental of FIND office premises in Geneva, India and Vietnam and are recoverable in accordance with the rental contract upon vacation of the premises.

2.4 Foreign currency

Accounting records are maintained in US dollars (USD). Revenue and expenditures in other currencies are recorded in USD approximating actual rates in effect at the time of the transaction. Year-end balances for assets and liabilities in other currencies are translated into US dollars at rates of exchange prevailing at balance sheet date. At 31 December 2019, the rate of exchange used for the Swiss franc, the main foreign currency for 2019, was USD/CHF = 0.968 (2018 – 0.986).

2.5 Recognition of revenue

Grants requiring the return of unspent funds are recorded in accordance with the principle of matching related revenues and expenses in the same period. Unused funds from such grants at the end of the period are recorded in the balance sheet under deferred revenue and recognised as revenue in future periods.

Grants which do not require unspent funds to be returned are recognised in the statement of revenue and expenditure at the time when FIND takes control of the funds.

Service revenue is recognised when the service is rendered.

2.6 Classification of restricted funds

Restricted funds are comprised of funds that are subject to restrictions in purpose as determined by third parties. The portion of restricted funds that are not used during the year or deferred, is recognised in the balance sheet through allocation to restricted funds and as a reduction of the result for the year. Conversely, when such funds are used in subsequent years, they will be recognised in the statement of revenue and expenditure through the use of funds.

2.7 Donations in-kind

Donations in-kind are not recorded but disclosed in the notes to the financial statements based on information provided by partners. They are valued at the price FIND would have had to pay if the goods or services were to be provided in exchange for payment under usual contractual terms. Services rendered or goods transferred to FIND must exclude any monetary transfer and must be clearly identifiable to a FIND project.

2.8 Consolidation

The following entities' results have been included in the consolidated financial statements:

FIND India and FIND Dx in South Africa.

The foundation's financial statements are consolidated according to the full consolidation method. All inter-company investments, balances and transactions have been eliminated.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2019

(all amounts in US dollars)

3. Grant revenue

The breakdown of grant revenue by area of activity is shown below:

	2019	2018
HQ activities	44,728,037	38,657,536
India access activities	10,539,363	20,518,762
South Africa activities	574,742	337,429
Total grant revenue	55,842,142	59,513,727

4. Donations received

During 2019, the following donations were received from donors (*other currency amounts are converted to USD at exchange rates on date of receipt*):

	2019	2018
Department for International Development (DFID), UK	16,720,202	9,335,553
The Bill and Melinda Gates Foundation	9,101,058	6,838,924
UNITAID	6,850,530	9,651,846
Department for Health and Social Care, UK	6,644,906	4,134,325
The Global Fund to Fight AIDS, Tuberculosis and Malaria	6,445,231	7,341,443
Australian Department of Foreign Affairs and Trade	5,225,944	2,825,925
Global Health Innovative Technology Fund (GHIT), Japan	2,038,112	1,810,272
Government of India, Ministry of Health & Family welfare, The Central TB Division	1,978,575	1,498,432
Dutch Ministry of Foreign Affairs (DGIS), Netherlands	1,706,176	2,592,280
Swiss Agency for Development and Cooperation	1,635,678	1,773,372
European and Developing Countries Clinical Trials Partnership (EDCTP) Association	671,277	346,145
Fondation Botnar	300,300	502,008
Federal Ministry of Education And Research (BMBF) through KfW, Germany	-	5,731,724
Médecins Sans Frontières	-	701,925
Other - amounts under \$500,000	3,652,434	2,467,753
Total contributions received	62,970,423	57,551,927

Donor agreements in effect as at 31 December 2019 provide for a total of USD 91 million to be paid to FIND between January 2020 and June 2023.

In accordance with Swiss GAAP RPC 21, donations are recognised as revenue, when FIND has a control over the funds. As such, contributions received may differ from grant revenue.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2019

(all amounts in US dollars)

5. Donations in-kind

FIND operations are funded through financial contributions and donations. In addition to financial contributions, generous partners, private companies and academic groups provide FIND with goods and services at no cost as donations in-kind. The analysis of goods and services received is as follows:

	2019	2018
Tuberculosis	564,593	690,597
AMR and Outbreaks	290,591	-
Access	293,666	-
Fever and Malaria	1,362,554	3,846,367
Neglected tropical diseases	953,615	971,325
HCV and HIV	383,804	1,067,184
Total donations in-kind	3,848,823	6,575,473

The above amounts include 31% for infrastructure and supplies, 46% for personnel and consultants, 17% for partners and 6% for travel, (2018 - 50% for infrastructure and supplies 47% for personnel and consultants, 1% for partners and 2% for travel).

In-kind contributions are reported above based upon information provided by our partners and are valued at the price FIND would have to pay in an arm's length transaction.

6. Expenditure by cost type

The breakdown of programme and supporting services by expense type and area of activity is shown below:

2019	HQ activities	India access activities	South Africa activities	Total
Project partners	18,384,210	939,557	185,826	19,509,593
Personnel	11,709,060	61,863	312,949	12,083,872
Consultants	7,590,570	2,748,409	26,958	10,365,937
Travel	2,217,035	557,067	14,339	2,788,441
Equipment	788,046	1,918,206	1,538	2,707,790
Supplies and other expenses	4,461,542	4,202,318	7,397	8,671,257
Total expenditure	45,150,463	10,427,420	549,007	56,126,890

2018	HQ activities	India access activities	South Africa activities	Total
Project partners	16,002,845	282,021	-	16,284,866
Personnel	11,111,344	78,994	279,753	11,470,091
Consultants	5,566,514	2,253,846	652	7,821,012
Travel	1,600,754	332,266	40,198	1,973,218
Equipment	671,071	14,772,184	33	15,443,288
Supplies and other expenses	3,671,016	2,773,383	11,564	6,455,963
Total expenditure	38,623,544	20,492,694	332,200	59,448,438

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2019

(all amounts in US dollars)

6. Expenditure by cost type (continued)

Note: India activities includes supporting services incurred in India

Commitments at 31 December 2019 for future payments to partners under contracts signed up until 31 December 2019 total USD 7,386,452 (2018 – USD 13,621,458).

The annual average number of full-time personnel equivalents for the reporting year, as well as the previous year, did not exceed 250.

7. Remuneration

The total amount of remuneration paid to the members of the leadership team amounts to CHF 1,079,893 (2018 – CHF 1,033,681). Remuneration is consistent with requirements, qualifications, responsibility and work performance

Members of the Foundation board do not have a paid relationship with the organisation as defined by labour law. Travel expenses incurred are reimbursed based upon receipts.

8. Cash and cash equivalents

Cash and cash equivalents as at 31 December were as follows:

	2019	2018
Petty cash	2,054	952
Bank current accounts	30,862,508	29,776,833
Short-term deposits	10,007,246	8,037,423
Total cash and cash equivalents	40,871,808	37,815,208

9. Deferred revenue

Deferred revenue represents assets to which the donor has attached a condition specifying the right to return of the transferred funds. As such, revenue on these grants is deferred until the condition is met and the right to the return of the funds is extinguished and will then be recognised in the income statement as grant revenue.

The following table shows the breakdown of these funds by program.

	2019	2018
Tuberculosis	9,919,691	8,086,958
AMR & Outbreaks	11,461,390	5,463,412
Fever and Malaria	3,960,349	3,343,455
Neglected tropical diseases	2,956,890	3,669,950
HIV and HCV	2,375,164	4,865,153
Access and other	6,825,727	2,852,316
Total deferred revenue	37,499,211	28,281,244

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2019
(all amounts in US dollars)

10. Pension fund liabilities

USD 3,468 was due to the pension fund as at 31 December 2019 (2018 – USD 249,830).

11. Rent commitments

At 31 December 2019, FIND had future rent commitments totalling USD 783,297 up to 31 May 2021 (2018 – USD 833,219 up to 31 May 2020). Of this amount, USD 562,605 is due within 12 months (2018 – USD 611,314).

12. Operating lease commitments

At 31 December 2020, FIND had future rent commitments on operating leases totalling USD 16,480 up to 31 October 2020 (2018 – USD 35,616 up to 31 October 2020), USD 16,480 of which is due within 12 months (2018 – USD 19,427).

13. Foundation capital

The Endowment Capital of CHF 50,000 is fully subscribed and equates to USD 40,430 at the rate of exchange on the date of payment.

14. Events subsequent to 31 December 2019

On 11 March 2020, the World Health Organisation declared the Coronavirus (COVID-19) outbreak to be a pandemic in recognition of its rapid spread across the globe, with over 150 countries now affected. Many governments are taking increasingly stringent steps to help contain or delay the spread of the virus. Currently, there is a significant increase in economic uncertainty which is, for example, evidenced by more volatile asset prices and currency exchange rates.

For the reporting date 31 December 2019, the Coronavirus outbreak and the related measures are non-adjusting events. Consequently, there is no impact on recognition and measurement of assets and liabilities. However, based on the limitations on movement imposed by many governments to protect their populations, we expect some delays in our project activities in 2020. It is not at present known the extent of the delays but we have already received assurance from some donors that we will be allowed some time extensions to complete projects already started or planned. We are also working directly on providing diagnostic solutions to control COVID-19 resulting in some reassignment of staff from other projects where applicable. Our foreign exchange exposure at end December is considered minimal due to natural hedges at the balance sheet date.



FIND 
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